K120987

JUN - 6 2012

510(k) Summary

Date Prepared March 30, 2012

Submitter

Medtronic, Inc.
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Establishment Registration Number: 2184009

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Device Name and Classification

Trade Name:	DLP® Silicone Single Stage Venous Cannula with Inflatable Cuff
Common Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Classification:	Class II

Predicate Device

K854487	Venous Return Cannula with Cuff

Device Description

The DLP® Silicone Single Stage Venous Cannula with Inflatable Cuff is used during cardiopulmonary bypass surgical procedures for collecting and directing blood from the right side of the heart via the superior and inferior vena cava into the bypass circuit. These cannulae are comprised of a wire-wound, kink-resistant silicone cannula body with a nominal tip outer diameter of 37Fr and an overall length of 15 inches. The DLP® Silicone Single Stage Venous Cannula with Inflatable Cuff model features a manually inflatable silicone inflatable cuff near the distal tip of the device which, once inflated, assists in maintaining the position of the device throughout the cardiopulmonary bypass procedure.

Indications for Use

These cannulae are intended for collection of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery up to six hours or less.

Contraindications

This device is contraindicated for long-term use. Do not use for extended terms such as Ventricular Assist procedures.

Comparison to Predicate Device

A comparison of the modified device to the currently marketed DLP® Silicone Single Stage Venous Cannula with Inflatable Cuff notes the following similarities:

- Same intended use
- Same operating principle
- Same technological characteristics
- Same design features
- Same shelf life

Conclusion

Medtronic has demonstrated that the modifications to the DLP® Silicone Single Stage Venous Cannula with Inflatable Cuff described in this submission result in a substantially equivalent device because the fundamental scientific technology, the intended use, operating principle and design features are unchanged since the predicate device. Any noted differences do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 6 2012

Medtronic, Inc.
c/o Ms. Jacqueline A. Hauge
Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K120987
Trade/Device Name: DLP Silicone Single Stage Venous Cannula with Inflatable Cuff
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: May 10, 2012
Received: May 11, 2012

Dear Ms. Hauge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120987

Device Name: DLP® Silicone Single Stage Venous Cannula with Inflatable Cuff

Indications For Use:

These cannulae are intended for collection of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery up to six hours or less.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number k120987